

REMARKS

The specification is amended herein to correct an inadvertent typographical error in cited U.S. Patent No. 5,196,190.

A Supplemental Information Disclosure Statement and a Supplemental Information Disclosure Statement List are filed herewith.

Claims 1, 3, 4, 6-17, and 21-27 are pending. Claims 11 and 22 have been amended to more clearly claim what Applicants consider to be their invention. Claims 1, 15, and 23 are amended herein to correct inadvertent typographical errors. Claims 2, 5, and 18-20 have been canceled. Claims 1, 3, 4, 6-10 and 27 have been withdrawn as being drawn to a non-elected invention. Claims 11-17 and 21-26 are under consideration. Support for these amendments can be found in the original claim language and throughout the specification, as set forth below. It is believed that these amendments add no new matter. In light of these amendments and the following remarks, Applicants respectfully request reconsideration of this application, entry of these amendments, and allowance of the claims to issue.

35 U.S.C. §112, first paragraph

Claim 11 is rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. The Office Action states that the claim contains subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the invention. Specifically, the Office Action states that as amended, Claim 11 recites the term “continuous” and that support for this amendment is lacking, and the addition of the term is new matter.

Claim 11 is amended herein by deleting the term “continuous.” Applicants submit that deleting the term “continuous” overcomes this rejection and respectfully request withdrawal of this rejection.

35 U.S.C. § 102

Claims 11-17 and 24-26 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Patent No. 6,13,794 (Chaudhuri). The Office Action states that Chaudhuri

discloses a topical formulation for the treatment of fungal diseases comprising the hydrophilic polymer matrix of instant Claim 11, the active agent of instant Claim 11, the humectant of instant Claim 11, the moisture content of instant Claim 11, the direct contact with an unguar structure of instant Claim 11, the organic acid of instant Claim 11, the moisture management system of instant Claim 12, the attachment element of instant Claim 13, the polyacrylamide of instant Claims 14 and 24-26, the citric acid of instant Claim 15, the polyethylene glycol of instant Claim 16, and the moisture content of instant Claim 17.

Applicants traverse this rejection as it is applied to the claims as amended.

A. Claim 11 is amended herein by adding the phrase “a flexible membrane.” Thus, amended Claim 11 recites “A composition comprising a flexible membrane comprising, a) a hydrophilic polymer matrix; b) at least one active agent; c) at least one humectant; and d) a moisture content in the hydrophilic polymer matrix composition effective to create a diffusion gradient from the hydrophilic polymer matrix composition to an unguar structure, wherein the hydrophilic polymer matrix directly contacts the unguar structure and moisture and at least one active agent are transferred by the diffusion gradient from the hydrophilic polymer matrix composition to the unguar structure, and wherein at least one active agent comprises a weak organic acid.” Support can be found in the specification on page 21, lines 7-23. Specifically, the specification incorporates by reference U.S. Patent No. 5,196,190 to Nangia.

Nangia teaches “a wound dressing in the form of a flexible membrane. The membrane is particularly suited for use as a skin substitute where the skin of a patient has been removed or damaged by for example abrasion or burning. In the broadest aspect of this embodiment of the invention, the membrane includes a natural or synthetic polymer and a non-gellable polysaccharide.” See Nangia, col. 3, lines 40-47.

For a prior art reference to anticipate a claimed invention, each and every element of the claimed invention must be disclosed in that single reference. Further, the disclosure in that single reference must be enabling. If one element of the claimed invention is not disclosed in the prior art reference, there is no anticipation. It is settled law that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently.”

Verdegaal v. Union Oil, 814 F2d. 628, 2 USPQ2d 1051 (Fed. Cir. 1987).

Chaudhuri does not teach a composition comprising a flexible membrane comprising, a) a hydrophilic polymer matrix; b) at least one active agent; c) at least one humectant; and d) a

moisture content in the hydrophilic polymer matrix composition effective to create a diffusion gradient from the hydrophilic polymer matrix composition to an ungual structure, wherein the hydrophilic polymer matrix directly contacts the ungual structure and moisture and at least one active agent are transferred by the diffusion gradient from the hydrophilic polymer matrix composition to the ungual structure, and wherein at least one active agent comprises a weak organic acid.

In contrast, Chaudhuri makes no mention of a composition comprising a flexible membrane comprising a hydrophilic polymer matrix, at least one active agent, and at least one humectant.

Because Chaudhuri does not teach each and every element of amended Claim 11, there is no anticipation. Therefore, Applicants respectfully request withdrawal of this rejection and allowance of amended Claim 11 and dependent Claims 12-17.

B. Claim 22 is amended herein by adding the phrase “a flexible membrane.” Thus, amended Claim 22 recites “A composition, comprising a flexible membrane comprising: a) a hydrophilic polymer matrix; b) at least one active agent; c) at least one humectant; and d) a moisture content in the composition effective to create a diffusion gradient from the composition to an ungual structure, wherein moisture and at least one active agent are transferred from the hydrophilic polymer matrix composition to the ungual structure when the composition contacts the ungual structure, and wherein at least one active agent comprises a weak organic acid in a concentration of about 0.1% to about 16% w/w.” Support can be found in the specification on page 21, lines 7-23. Specifically, the specification incorporates by reference U.S. Patent No. 5,196,190 to Nangia.

Nangia teaches “a wound dressing in the form of a flexible membrane. The membrane is particularly suited for use as a skin substitute where the skin of a patient has been removed or damaged by for example abrasion or burning. In the broadest aspect of this embodiment of the invention, the membrane includes a natural or synthetic polymer and a non-gellable polysaccharide.” See Nangia, col. 3, lines 40-47.

Chaudhuri does not teach a composition, comprising a flexible membrane comprising: a) a hydrophilic polymer matrix; b) at least one active agent; c) at least one humectant; and d) a moisture content in the composition effective to create a diffusion gradient from the composition to an ungual structure, wherein moisture and at least one active agent are transferred from the

hydrophilic polymer matrix composition to the ungual structure when the composition contacts the ungual structure, and wherein at least one active agent comprises a weak organic acid in a concentration of about 0.1% to about 16% w/w.

In contrast, Chaudhuri makes no mention of a composition comprising a flexible membrane comprising a hydrophilic polymer matrix, at least one active agent, and at least one humectant.

Chaudhuri does not teach each and every element of amended Claim 22. Because Claims 24-26 depend from and have all of the limitations of amended Claim 22, Chaudhuri cannot anticipate Claims 24-26. Therefore, Applicants respectfully request withdrawal of this rejection and allowance of Claims 24-26.

35 U.S.C. 103

Claims 21-23 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,143,794 (Chaudhuri). The Office Action states that Chaudhuri teaches a topical formulation for the treatment of fungal diseases. The Office Action states that Chaudhuri provides a gel capable of delivering an antifungal through the nail barrier.

The Office Action concedes that Chaudhuri does not explicitly teach the percentages of instant Claims 21-23 but goes on to state that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results. The Office Action states that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a composition comprising a hydrophilic polymer matrix, at least one active agent, at least one humectant, and moisture content effective to create a diffusion gradient as taught by Chaudhuri. The Office Action goes on to state that “one of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it provides a gel capable of delivering an antifungal through the nail barrier as explained by Chaudhuri.” See Office Action, page 5, second paragraph.

Applicants traverse this rejection as it is applied to the claims as amended.

Claim 21 depends from amended Claim 11 and includes all of the limitations of amended Claim 11. Claim 23 depends from amended Claim 22 and includes all of the limitations of amended Claim 22.

Claim 11 is amended herein by adding the phrase “a flexible membrane.” Thus, amended Claim 11 recites “A composition comprising a flexible membrane comprising, a) a hydrophilic polymer matrix; b) at least one active agent; c) at least one humectant; and d) a moisture content in the hydrophilic polymer matrix composition effective to create a diffusion gradient from the hydrophilic polymer matrix composition to an ungual structure, wherein the hydrophilic polymer matrix directly contacts the ungual structure and moisture and at least one active agent are transferred by the diffusion gradient from the hydrophilic polymer matrix composition to the ungual structure, and wherein at least one active agent comprises a weak organic acid.” Support can be found in the specification on page 21, lines 7-23. Specifically, the specification incorporates by reference U.S. Patent No. 5,196,190 to Nangia.

Nangia teaches “a wound dressing in the form of a flexible membrane. The membrane is particularly suited for use as a skin substitute where the skin of a patient has been removed or damaged by for example abrasion or burning. In the broadest aspect of this embodiment of the invention, the membrane includes a natural or synthetic polymer and a non-gellable polysaccharide.” See Nangia, col. 3, lines 40-47.

Claim 22 is amended herein by adding the phrase “a flexible membrane.” Thus, amended Claim 22 recites “A composition, comprising a flexible membrane comprising: a) a hydrophilic polymer matrix; b) at least one active agent; c) at least one humectant; and d) a moisture content in the composition effective to create a diffusion gradient from the composition to an ungual structure, wherein moisture and at least one active agent are transferred from the hydrophilic polymer matrix composition to the ungual structure when the composition contacts the ungual structure, and wherein at least one active agent comprises a weak organic acid in a concentration of about 0.1% to about 16% w/w.” Support can be found in the specification on page 21, lines 7-23. Specifically, the specification incorporates by reference U.S. Patent No. 5,196,190 to Nangia.

Nangia teaches “a wound dressing in the form of a solid flexible membrane. The membrane is particularly suited for use as a skin substitute where the skin of a patient has been removed or damaged by for example abrasion or burning. In the broadest aspect of this embodiment of the invention, the membrane includes a natural or synthetic polymer and a non-gellable polysaccharide.” See Nangia, col. 3, lines 40-47.

It is the burden of the Office to provide a rationale from the prior art for making the specific claimed modification or combination. The Supreme Court recently addressed nonobviousness of “combination” inventions in *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (*KSR*). The Court confirmed that it is legally insufficient to merely point to the various recited elements. Instead, the Office must identify the basis for the alleged modification or combination by one of ordinary skill to arrive at the claimed invention.

As is clear from cases such as *Adams*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

KSR at *37-*38 (emphasis by underlining added).

Moreover, the Supreme Court opined that conclusory statements cannot provide an adequate basis for the alleged modification or combination; the reasoning must be explicit.

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) (“Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”).

KSR at *36-*37 (emphasis by underlining added).

Absent this explicit reasoning to support the basis for the modification or combination, the alleged modification or combination cannot support a *prima facie* obviousness rejection for the following reasons.

The Supreme Court has reaffirmed the Graham factors for determination of obviousness under 35 U.S.C. 103(a) in *KSR*. The four factual inquiries under *Graham* require examination of: (1) the scope and contents of the prior art; (2) the differences between the prior art and the claims in issue; (3) the level of ordinary skill in the pertinent art; and (4) the objective evidence of secondary consideration. *Graham v. John Deere (Graham)*, 383 U.S. 1, 17-18, 149 USPQ 459, 467 (1966); see also 35 U.S.C. § 103 (2000).

The Court has further recognized that the requirement for a teaching, suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, which was established by the Court of Customs and Patent Appeals, provides a helpful insight for determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a). In addition, the Court maintained that any analysis supporting a rejection under 35 U.S.C. § 103(a) should be made explicit, and that it is “important to identify reasons that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements” in the manner claimed, because “inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *KSR* at 14, 15.

Further, courts have generally recognized that a showing of a *prima facie* case of obviousness necessitates three requirements: (i) some suggestion or motivation, either in the references themselves or in the knowledge of a person of ordinary skill in art, to modify the reference or combine the references’ teachings; (ii) a reasonable expectation of success; and (iii) the prior art references must teach or suggest all of the claim limitations. See e.g., *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999); *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998); *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

The Office has failed to make a *prima facie* case of obviousness. As argued above, Chaudhuri does not teach each and every element of amended Claims 11 and 22, nor does Chaudhuri render Claims 21-23 obvious for the following reasons.

As shown above, Chaudhuri does not teach a composition comprising a flexible membrane comprising, a) a hydrophilic polymer matrix; b) at least one active agent; c) at least one humectant; and d) a moisture content in the hydrophilic polymer matrix composition effective to create a diffusion gradient from the hydrophilic polymer matrix composition to an

ungual structure, wherein the hydrophilic polymer matrix directly contacts the ungual structure and moisture and at least one active agent are transferred by the diffusion gradient from the hydrophilic polymer matrix composition to the ungual structure, and wherein at least one active agent comprises a weak organic acid, as recited in amended Claim 11.

Moreover, Chaudhuri does not teach a composition, comprising a flexible membrane comprising: a) a hydrophilic polymer matrix; b) at least one active agent; c) at least one humectant; and d) a moisture content in the composition effective to create a diffusion gradient from the composition to an ungual structure, wherein moisture and at least one active agent are transferred from the hydrophilic polymer matrix composition to the ungual structure when the composition contacts the ungual structure, and wherein at least one active agent comprises a weak organic acid in a concentration of about 0.1% to about 16% w/w, as recited in amended Claim 22.

Not only does Chaudhuri not teach or suggest the claimed invention, Chaudhuri also teaches away from the claimed invention which discloses a flexible membrane that contains at least one active agent. Specifically, Chaudhuri teaches a “liquid or semi-solid antifungal composition, such as a cream, ointment, lotion, or gel (preferably a gel). . . .” See Chaudhuri, col. 4, lines 44-47. Moreover, in contrast to the instant invention which teaches including a non-gellable polysaccharide in the antifungal composition, Chaudhuri teaches “in addition to the antifungal compound and a pharmaceutically acceptable solvent, the composition of this invention also includes a gelling agent in an amount to form a gel.” See Chaudhuri, col. 6, lines 13-16.

Applicants are not arguing for a rigid application of the teaching-suggestion-motivation (TSM) rationale, which requires that a printed statement be present for a finding of obviousness. Instead, Applicants submit that the Supreme Court acknowledged that the TSM test was one of a number of valid rationales that could be used to determine obviousness. *KSR* at 1727 (2007); see *MPEP* 2141; *In re Kahn*, 441 F.3d 977, 986, 78 U.S.P.Q. 2d 1329, 1335 (Fed. Cir. 2006). Applicants respectfully submit that there is no suggestion or motivation to make the proposed modification of an antifungal composition taught in Chaudhuri to make the claimed invention.

Modification of the antifungal composition taught in Chaudhuri to create an antifungal composition as taught in the instant application would render the Chaudhuri patent unsatisfactory

for its intended purpose. According to the U.S. Court of Appeals for the Federal Circuit, "[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed invention." (*In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 125 (Fed. Cir. 1984); see MPEP 2143.01). Attempts to create an antifungal composition comprising a flexible membrane which contains a non-gellable polysaccharide, as disclosed in the instant application, would result in an antifungal composition unsatisfactory for the intended purpose of the composition taught in Chaudhuri.

A person of ordinary skill in the art, at the time the instant application was filed, would not be motivated to modify the teachings of Chaudhuri to create the claimed invention. The claimed invention is not obvious in view of the disclosure of Chaudhuri. Therefore, the Examiner's rejection of Claims 21-23 of the instant application on the basis that it would be obvious for a person of skill to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results is rendered moot.

CONCLUSION

The foregoing is a complete response to the Office Action dated February 19, 2009. Applicants respectfully submit that Claims 11-17 and 21-26 are patentable. Early and favorable consideration is solicited.

Applicants file this response solely to facilitate prosecution. As such, Applicants reserve the right to pursue claims of broader or similar scope as originally filed in a continuation application or other application after allowance of the present application. Applicants do not concede that the current or past rejections are correct and reserve the right to challenge such rejections later in prosecution or on appeal. Accordingly, any amendment, argument, or claim cancellation is not to be construed as abandonment or disclaimer of subject matter.

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending claims are believed to be warranted, and such action is respectfully requested. The Examiner is invited to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issuance.



ATTORNEY DOCKET NO.: 01307.0004U2
APPLICATION NO.: 10/630,627

A credit card payment submitted *via* Form PTO-2038 in the amount of \$670.00

(representing 490.00 for a two-month Extension of Time and \$180.00 for the fee under 37 C.F.R. § 1.17(p)), a Request for Extension of Time, a Supplemental Information Disclosure Statement, and a Supplemental Information Disclosure Statement List are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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ATTENTION!!! ATTENTION!!! ATTENTION!!!

The attached documents are provided as part of **APPENDIX A**, which is included as part of a **Supplemental Information Disclosure Statement** for the following U.S. patent application.

Application No.: 10/630,627

Filing Date: July 29, 2003

For: METHODS AND COMPOSITIONS FOR TREATMENT OF DERMAL CONDITIONS

Inventor: A. Schmid

Confirmation No.: 9066

Art Unit: 1615

Examiner: Maley et al.

Attorney Docket No.: 01307.0004U2

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ATTENTION!!! ATTENTION!!! ATTENTION!!!

The attached documents are provided as part of **APPENDIX A**, which is included as part of a **Supplemental Information Disclosure Statement** for the following U.S. patent application.

Application No.: 10/630,627

Filing Date: July 29, 2003

For: METHODS AND COMPOSITIONS FOR TREATMENT OF DERMAL CONDITIONS

Inventor: A. Schmid

Confirmation No.: 9066

Art Unit: 1615

Examiner: Maley et al.

Attorney Docket No.: 01307.0004U2

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